UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY PATENT LITIGATION	No. 04-MDL-01592 This Document Relates To: No. 03-CV-11329-MLW

OPPOSITION OF BIOGEN IDEC MA INC. AND GENZYME CORPORATION TO COLUMBIA UNIVERSITY'S MOTION TO DISMISS

REDACTED

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

FEDERAL CASES

CONSTITUTION

FEDERAL STATUTES

STATE STATUTES

OTHER AUTHORITIES

Biogen Idec MA Inc. ("Biogen") and Genzyme Corporation ("Genzyme") respectfully submit this brief in opposition to Columbia University's Emergency Motion to Dismiss for Lack of Subject Matter Jurisdiction.[1]

INTRODUCTION

On September 1, 2004, defendant The Trustees of Columbia University in the City of New York ("Columbia") filed with this Court a limited "Covenant Not to Sue" ("Covenant") stating it would not assert any claim of patent infringement or seek royalties based upon U.S. Patent No. 6,455,275 (the "'275 patent") "as it presently reads," against any of the named plaintiffs in the present litigation for any "product that was made, used, offered for sale, sold, or imported" *prior to September 1, 2004*. In the very same filing, Columbia reiterated its infringement contentions: Columbia "*in no way concedes that the '275 patent is not infringed, invalid or unenforceable,*" and, to the contrary, "*categorically rejects*" plaintiffs' claims (emphasis added). Columbia has expressly refused to extend the Covenant past September 1, 2004, has expressly excluded corporate affiliates from the protection of the Covenant, and has expressly excluded from the Covenant any patent that issues on pending U.S. Patent Application No. 08/477,159 (the "'159 application"), even if it contains claims identical or substantially identical to the '275 claims. Nevertheless, Columbia argues that there is no longer any case or controversy between the parties.

Columbia's Covenant not to seek royalties or damages for activities prior to September 1, 2004, comes six months after it gave notice of termination of plaintiffs' licenses and vigorously opposed plaintiffs' costly efforts to persuade this Court to enjoin such termination. The Court

---

[1] Abbott Bioresearch Center, Inc. ("Abbott), a third plaintiff in this case, is filing its own brief in opposition to Columbia's motion to dismiss.

declined to enjoin the termination, and instead ruled that the licenses were "deemed terminated as of April 2004 for Biogen and as of May 2004 for Genzyme." August 13, 2004, Memorandum and Order, at 3 (Biogen Docket No. 84).

Columbia's sudden change of tactics comes just weeks after the Court's decision permitting termination. The reason for Columbia's "emergency" request to end the litigation is not hard to discern. In denying plaintiffs' motion for preliminary injunction, the Court concomitantly found that plaintiffs had made a "strong showing" of likelihood of success on their challenge to Columbia's '275 patent. Columbia wants to get out of this Court, and it wants to get out fast—before the infirmities in its patent are exposed on the expedited schedule set by the Court. Lest there be any doubt about Columbia's forum shopping goals, they are made clear on the very first page of its brief, where it asks this Court to remand all remaining claims in the multidistrict litigation ("MDL") to the district courts in which they were originally filed. These claims include two claims for breach of contract that will themselves require determination of the validity and enforceability of the '275 patent, plus Columbia's own counterclaim against Amgen, Inc. and Immunex Corp. for a declaratory judgment with respect to ongoing royalty obligations and the asserted validity and enforceability of the '275 patent. Columbia's request for the remand of claims to district courts other than this one flies in the face of its earlier insistence to the MDL panel that all these claims should be consolidated in a single MDL proceeding.

Columbia's attempt to fend off judicial scrutiny of its discredited patenting strategy asserts that there is no longer any controversy between the parties within the meaning of Article III of the United States Constitution. As demonstrated below, Columbia's jurisdictional theory is baseless. Unlike the plaintiffs in the cases Columbia cites on the effect of a covenant not to sue, and unlike Ultratech in *SVG Lithography Systems, Inc. v. Ultratech Stepper, Inc.*, No. C.A. 01-

11766-MLW, 2004 WL 1948742 (D. Mass. Mar. 6, 2004), Biogen and Genzyme are actively engaging in, and have concrete plans to continue engaging in, substantial and ongoing activity that potentially infringes the '275 patent and is expressly excluded from the Covenant.

As is apparent from the Covenant itself and Columbia's follow-up clarifications, Columbia is unwilling to let go of the '275 patent for the remainder of its 17-year term, and instead wants to leave it hanging, like the sword of Damocles, over the head of any plaintiff unwilling to acquiesce in Columbia's settlement demands. In these circumstances, Columbia cannot escape this Court's determination of the patent's validity and enforceability. Moreover, on the basis of Columbia's actions over the past six months, plaintiffs have asserted additional claims against Columbia, including for breach of contract and patent misuse, that will require determination of the patent's validity and enforceability in any event. There is no question that there is an actual Article III controversy between the parties capable of resolution by this Court. Columbia's motion to dismiss must be denied.

FACTUAL BACKGROUND

The patent application

In the late 1970s, Richard Axel, Michael H. Wigler, and Saul J. Silverstein, scientists at Columbia University, carried out research on methods of inserting genes that code for desired proteins into the DNA of certain types of cells. Specifically, the Columbia scientists conducted experiments in cotransformation, a process of inserting into a cell *both* (a) a gene that codes for a desired protein, and (b) a gene that codes for a "selectable marker" that helps to confirm that the cell has been successfully transformed. By transforming a host cell with a gene encoding for a desired protein, scientists can induce the cell to manufacture proteins, including human proteins that can be used as therapeutic drugs.

Axel, Wigler, and Silverstein filed a patent application in February 1980. *See* U.S. Patent No. 6,455,275 col. 1, ll. 5–20 (issued Sept. 24, 2002) (Tab 1).[2] This application led to the issuance of three patents, containing more than 100 claims, that expired on August 16, 2000. The same 1980 patent application led to the issuance of the '275 patent in September 2002. *See id.* The '275 patent claims (a) cotransformed CHO cells, (b) methods of producing proteins using cotransformation, and (c) DNA "constructs" for use in cotransforming CHO cells. *See id.* cols. 40–42. The '275 patent will not expire until 2019.

The licenses and demands for payment under the '275 patent

Columbia granted non-exclusive licenses under the original Axel patents to Biogen in 1993 and Genzyme in 1994. Biogen License § 2(a) (Dec. 1993) (Tab 2); Genzyme License § 2(a) (Feb. 1994) (Tab 3). Royalties due under these licenses are calculated as a percentage of sales of "End Products," such as therapeutic drugs, if the manufacture, use or sale of the product is covered by a claim of a licensed patent. Biogen License § 3(d)–(g) (Tab 2); Genzyme License § 3(d)–(g) (Tab 3). Biogen and Genzyme paid approximately $60 million to Columbia under their licenses during the term of the first three Axel patents. Columbia also licensed the patents to other biotechnology companies, reaping hundreds of millions of dollars in royalties. Biogen and Genzyme expected their royalty obligations to cease with the expiration of the patents on August 16, 2000.

Shortly after the '275 patent issued, Columbia transmitted copies of the new patent to Biogen and Genzyme, stating that it was "part of the Licensed Patent Rights" under the terms of

---

[2] Citations to new record sources are to the Appendix to Opposition of Biogen Idec MA Inc. and Genzyme Corporation to Columbia University's Motion to Dismiss, filed herewith. Citations to materials appearing in that Appendix are either to the Declaration of Carla M. Levy contained therein, or to materials appearing behind a numbered tab. In the latter case, the material will be cited by title and tab number.

their licenses. *See* Letters from Scot Hamilton, Senior Dir., Columbia Univ. Sci. & Tech. Ventures, to Biogen, Inc. and to Genzyme Corp. (Oct. 15, 2002) ("'275 Announcement Letters") (Tab 4). By letter to Biogen dated October 3, 2002, Columbia advised Biogen of the issuance of the '275 patent and noted that "Columbia does not agree" that Biogen's last payment was "its last royalty owed." *See* Letter from Debbie McMurray, Biogen, Inc. to Columbia Innovation Enters. (Sept. 26, 2002) ("Royalty Letter") (Tab 5); Letter from Scot G. Hamilton to Debbie McMurray, Biogen, Inc. (Oct. 3, 2002) (Tab 6). Thus, although plaintiffs believed that their royalty obligations to Columbia had expired, Columbia demanded royalty payments for another seventeen years, the term of the '275 patent.

The lawsuit and motions to transfer

Biogen, Genzyme and Abbott Bioresearch Center, Inc. ("Abbott") filed suit in July 2003, seeking a declaration that the '275 patent is invalid and unenforceable and that they do not owe royalties under their respective license agreements with Columbia. Other licensees brought similar suits.

Columbia first filed motions to transfer venue to the Northern District of California under 28 U.S.C. § 1404, taking the position that multidistrict proceedings were inappropriate. *See* Def.'s Mem. Supp. Mot. for § 1404(a) Transfer, at 13 (Biogen Docket No. 17) ("Despite the common questions of law and fact in the four lawsuits against Columbia, Multidistrict Litigation ... would not address Columbia's concerns."). Columbia later reversed itself and withdrew its § 1404 motion in this and other cases in favor of a motion to the Judicial Panel on Multidistrict Litigation ("JPML") for multidistrict consolidation of the cases under 28 U.S.C. § 1407. In support of consolidation, Columbia argued that "[t]he allegations in each of the lawsuits are fundamentally the same" and that § 1407 transfer would "serve the interests of all the parties and

witnesses while furthering judicial economy ...." *See* Columbia's Br. Supp. Mot. for § 1407, at 1–2, *In re Columbia Univ. Patent Litig.*, 313 F. Supp. 2d 1383 (J.P.M.L. 2004) (MDL No. 1592) (Tab 7); *see also* Columbia Reply Br. Supp. Mot. for § 1407 Transfer, at 1–2, *In re Columbia Univ. Patent Litig.* (Tab 8). The JPML granted Columbia's motion for transfer, but transferred the cases to the District of Massachusetts instead of Columbia's preferred forum, the Northern District of California.

Termination of the licenses

On March 9, 2004, Columbia sent letters to Biogen and Genzyme asserting that they were in breach of their license agreements for (1) failure to pay royalties for use of the technology claimed in the '275 patent and (2) failure to submit the quarterly sales reports required under their licenses. Letter from Michael J. Cleare to Vice President, Marketing, Biogen, Inc. ("Biogen Termination Letter") (Tab 9); Letter from Michael J. Cleare to Vice President, General Counsel, Genzyme Corp. ("Genzyme Termination Letter") (Tab 10). Columbia's letter to Biogen included a third ground: (3) failure to pay all fees. Both letters purported to provide notice that Biogen and Genzyme's respective licenses would terminate if royalties were not paid within the specified cure period.

Neither Biogen nor Genzyme took any steps to cure any of the breaches asserted in the termination letters. Neither has submitted to Columbia any quarterly sales reports since they made their last payments under the original three Axel patents in 2002. Declaration of Debbie McMurray[3]; Declaration of Jennifer Dupré.

---

[3] Witness declarations are in the Appendix of Declarations for Opposition of Biogen Idec MA Inc. and Genzyme Corporation to Columbia University's Motion to Dismiss, filed herewith under seal.

Preliminary injunction and motion for stay

On April 7, 2004, Biogen and Genzyme moved for a preliminary injunction to enjoin the termination of their licenses, arguing that the termination was improper because the '275 patent is invalid for double patenting over the more than 100 claims already obtained by Columbia in its three earlier patent, and is unenforceable by reason of prosecution laches, noting that the patent had issued **twenty-two** years after the patent application upon which it was based, and would extend Columbia's patent monopoly to **thirty-nine** years. *See* Corrected Mem. Supp. Pls.' Joint Mot. for T.R.O. and Prelim. Inj., at 12–46 (Biogen Docket No. 38). Columbia adamantly opposed the preliminary injunction motion, maintaining that it was justified in terminating the licenses, and that the failure to permit Columbia to terminate the license would have devastating implications for academic research and licensing. *See* Columbia's Mem. Opp'n Mot. for Prelim. Inj., at 6–7, 16–18 (Biogen Docket No. 46).

While the preliminary injunction motion was pending, Columbia sought to stay this litigation in favor of resolving the double patenting issues in *ex parte* reexamination and reissue proceedings before the Patent and Trademark Office ("PTO"). *See* Columbia's Mot. to Stay, at 1 (Biogen Docket No. 51). At the time, Columbia represented to this Court that the two proceedings could be merged and would proceed expeditiously. Tr. of Oral Argument, at 90–91, *Biogen, Inc. v. Columbia University*, No. 03-11329 (D. Mass., hearing held June 22, 2004) ("June 22 Hearing Transcript") (Tab 15). The Court ultimately denied Columbia's motion to stay and plaintiffs' motion for preliminary injunction, instead establishing a fast track for resolution of the issue of the invalidity of the '275 patent for obviousness-type double patenting. Unbeknownst to the Court and contrary to its representation just weeks earlier, Columbia did not seek merger of the reexamination and reissue proceedings but rather moved to *stay*

reexamination of the patent pending the outcome of the reissue proceeding, evidently in the hope of stringing out its twenty-four years of patent prosecution still further. Petition to Stay *Ex Parte* Reexamination No 90/006,953 (July 7, 2004) (Tab 23).

In denying Biogen's and Genzyme's motion for preliminary injunction and permitting termination of the licenses, the Court nevertheless held that plaintiffs had made a "strong showing" of likelihood of success on the merits of their double patenting challenge, as well as their prosecution laches challenge. *See* August 13, 2004 Memorandum and Order, at 3, 19, 23 (Biogen Docket No. 84).

The Covenant

On September 1, 2004,[4] just weeks after the Court approved Columbia's termination of its license agreements with Biogen and Genzyme, Columbia reversed course and filed a limited "Covenant Not to Sue" for royalties or infringement up to the date of the Covenant. *See* Covenant, at 1 (Tab 11). The Covenant stated that Columbia will not pursue "any claim of patent infringement" or seek royalties on the '275 patent "as it presently reads," against any of the named plaintiffs in the ongoing multidistrict litigation, for any "product that was made, used, offered for sale, sold, or imported" prior to September 1, 2004. *See id.* (Tab 11). However, the Covenant also stated: "Columbia in no way concedes that the '275 patent is not infringed, invalid or unenforceable. To the contrary, Columbia categorically rejects all such claims by plaintiffs." *See id.* (Tab 11).

---

[4] The Covenant and the following day's "emergency" motion to dismiss for lack of subject matter jurisdiction came just days after plaintiffs had submitted three expert reports articulating in detail the experts' conclusions that the '275 patent is invalid for double patenting. Columbia's motion to dismiss sought to expedite the briefing and obtain dismissal of the case before the date on which Columbia would be required to serve a rebuttal expert report, further explaining Columbia's attempt to have the Court consider its motion on an "emergency" basis.

In subsequent letters clarifying the scope of the Covenant, Columbia reserved the right to sue for infringement or seek royalties with respect to various product development activity subsequent to September 1, 2004. *See* Letter from David I. Gindler to Counsel for Record for Plaintiffs (Sept. 10, 2004) ("Sept. 10 Letter") (Tab 12); Letter from David I. Gindler, Irell & Manella LLP, to Counsel for Record for Plaintiffs 1–2 (Sept. 17, 2004) ("Sept. 17 Letter") (Tab 13). For example, Columbia indicated that "[i]f a scientist working at a plaintiff creates for the first time after September 1, 2004, a DNA construct or a cotransformed cell, such as a first cotransformation with a DNA I encoding for a particular protein, the Covenant *does not extend* to such DNA construct or cotransformed cell, unless such protein encoded by the DNA construct or cotransformed cell was on sale by such plaintiff on or before September 1, 2004." Sept. 17 Letter, at 2 (Tab 13) (emphasis added). Columbia has also expressly reserved the right to sue affiliates and customers of the named plaintiffs for patent infringement and to seek royalties from them. Sept. 10 Letter, at 1 (Tab 12).

On September 13, 2004, Columbia wrote to Genzyme and Biogen "withdraw[ing] the notices of termination" of their licenses, but expressly preserving all grounds for termination other than failure to pay royalties on the '275 patent. Letters from David I. Gindler to Donald Ware (Sept. 13, 2004) ("License Letters") (Tab 14) ("Columbia is not waiving any grounds for termination of the License Agreement, except for the failure to pay royalties based on the '275 patent as it currently reads ...."). Columbia thus reserved the right to terminate the Biogen and Genzyme licenses at any time for any reason other than non-payment of royalties for pre-September 1, 2004 activities.

Research and development activities of Biogen and Genzyme

***** The following discussion, filed under seal, constitutes highly confidential competitive and sensitive information regarding current and ongoing research and development at Biogen and Genzyme and is supported by the accompanying Declarations of Dr. Holly Prentice and Dr. Kenneth Karey, also filed under seal. For this reason, Biogen and Genzyme have filed motions to impound and request that neither this discussion nor the Declarations be disclosed publicly, or even to each other or the other plaintiffs in this MDL litigation.**

Biogen's research and development activities

REDACTED

REDACTED

REDACTED

REDACTED

Genzyme's research and development activities

REDACTED

REDACTED

REDACTED

ARGUMENT

I. There Is An Actual Controversy With Respect To Plaintiffs' Declaratory Judgment Counts.

Columbia moves to dismiss Biogen's and Genzyme's complaint on the theory that, as a result of its Covenant, there is no "actual controversy" within the meaning of the Declaratory Judgment Act. The Declaratory Judgment Act provides a remedy whose jurisdictional scope is commensurate with the power of the federal courts under Article III of the Constitution. *See* U.S. Const. art. III, § 1, cl. 1; 28 U.S.C. § 2201(a); *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239–42 (1937). Subject matter jurisdiction over declaratory judgment counts depends on "whether facts alleged, under all the circumstances, show … a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941); *see*

Aetna, 300 U.S. at 239–42; *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed. Cir. 1988) (finding jurisdiction where a patentee sent letters stating that putative infringer was not a licensee and that patentee intended on enforcing its patent and commenced a related suit against a third party).

The Federal Circuit has adopted a two-prong test that can help in certain situations to assess whether the requisite "case" or "controversy" exists when a patent is challenged.[5] *See Fina Research S.A. v. Baroid Ltd.*, 141 F.3d 1479, 1481 (Fed. Cir. 1998); *Arrowhead*, 846 F.2d at 736. The test requires that there be both: "(1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Fina*, 141 F.3d at 1481 (quoting *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058 (Fed. Cir. 1995)); *see Arrowhead*, 846 F.2d at 736. Ultimately, the existence of a "case" or "controversy" turns upon the "totality of the circumstances." *See Arrowhead*, 846 F.2d at 736; *see also Md. Cas. Co.*, 312 U.S. at 273.

The Supreme Court has recognized the special importance of facilitating judicial resolution of patent invalidity issues, not only for those who may be charged with infringement but also for the "public at large." *See Cardinal Chem. Co., et al. v. Morton Int'l, Inc.*, 508 U.S. 83, 99–101 (1993); *see also Lear, Inc. v. Adkins,* 395 U.S. 653, 670 (1969) ("If [licensees] are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification."); *AIR-vend v. Thorne Industries, Inc.*, 625 F. Supp. 1123, 1128 (D. Minn.

---

[5] While meeting this two-prong test is sufficient to establish jurisdiction, it is not the only means by which one can establish subject matter jurisdiction over a declaratory judgment action. *Aetna*, 300 U.S. at 239–42.

1985) ("Not to allow [the patent holders] to avoid litigating the validity of the '225 patent is also in the public interest in that it may result in the removal of an invalid patent from the public domain and that it may promote, as is the purpose of any declaratory judgment action, the relatively speedy and inexpensive adjudication of a legal dispute without resort to coercive remedies.").

Columbia does not question the existence of an actual controversy at the time Biogen and Genzyme filed their complaint in this action, nor does it suggest that the Court lost subject matter jurisdiction at any time prior to September 1, 2004. Rather, Columbia argues that its September 1, 2004, Covenant divested the Court of jurisdiction over the instant plaintiffs' declaratory judgment actions and, in the past few days, it has raised the additional argument that its letter concerning the present status of Biogen's and Genzyme's licenses had the same effect. Columbia is wrong on both counts. *See* Columbia's Mem. Supp. Emergency Mot. to Dismiss, at 5–8 (MDL Docket No. 87); Letter from David I. Gindler, Irell & Manella LLP, to Claire Laporte, Foley Hoag LLP 1–2 (Sept. 20, 2004) ("*Gen-Probe* Letter") (Tab 19).

A. Columbia's Covenant Does Not Eliminate The Reasonable Apprehension That It Will Sue Biogen And Genzyme For Infringement Or Royalties Under The '275 Patent.

There can be no doubt that Columbia intends to sue Biogen and Genzyme on the '275 patent whenever it sees fit. In analyzing the "reasonable apprehension" issue, courts are to consider the "totality of the circumstances" and determine whether a patent holder's prior actions, viewed in their entirety, would lead the declaratory judgment plaintiff to a reasonable belief that litigation is likely to occur. *Arrowhead*, 846 F.2d at 736.

Here, the Covenant itself creates a reasonable apprehension of suit. In the Covenant, Columbia unequivocally states that the '275 patent is valid, enforceable and infringed. Yet it does not promise categorically never to sue on the patent—it states only that it will not sue with

respect to products sold on or before September 1, 2004. *See* Covenant, at 1 (Tab 11). In letters purporting to clarify the scope of the Covenant, Columbia makes further threatening statements, expressly excluding plaintiffs' affiliates from the Covenant, and carefully reserving its right to sue for royalties or infringement damages with respect to any product that was not on the market on or before September 1, 2004. *See id.* (Tab 11).

Moreover, Columbia's recent threats cannot be considered in the abstract. These statements come in the wake of an extremely contentious history. The totality of circumstances that create in Biogen and Genzyme a reasonable apprehension of suit includes, for example:

- Columbia adamantly insisted from 2002 to 2004 that more royalties were owed under Biogen's license, stating that, in light of the issuance of the '275 patent, "Columbia does not agree that Biogen's payment for the second quarter of 2002 [for the patents that expired in August 2000] is its last royalty owed"[6];
- Columbia asserted that the '275 patent is "part of the Licensed Patent Rights under which [the licensees] are licensed"[7];
- Columbia brought infringement claims against other licensees of the '275 patent[8];
- Columbia repeatedly stated, throughout its filings opposing the motion for preliminary injunction and supporting its motion to stay, that it will likely sue the plaintiffs for infringement[9];

---

[6] Royalty Letter (Tab 5).

[7] '275 Announcement Letters (Tab 4).

[8] Countercls. for Breach of Contract and Declaratory Relief ¶¶ 13–28, *Immunex Corp. v. Trs. of Columbia Univ.*, No. CV 03-4349-MRP(CWx) (C.D. Cal. filed Feb. 12, 2004) (Tab 17); Compl. for Declaratory Relief and Breach of Contract ¶¶9–17, *Trs. of Columbia Univ. v. Johnson & Johnson*, No. C 03-4875 PJH (N.D. Cal. filed Oct. 31, 2003) (Tab 18).

[9] *See* Columbia's Mem. Opp'n Mot. for Prelim. Inj., at 2, 5, 9, 11 (Biogen Docket No. 46); Columbia's Supplemental Mem. on the Propriety of an Inj., at 5 (Biogen Docket No.70); Columbia's Mem. Supp. Mot. to Stay, at 2, 10, 16, 17 (Biogen Docket No. 74); Columbia's Reply Mem. Supp. Mot. to Stay, at 9–10 (Biogen Docket No. 76).

- Columbia represented to this Court during oral argument that it believes that the licensees who are challenging its '275 patent are infringing, and that Columbia will likely assert infringement claims[10]; and

- Columbia sent notices of termination to both Biogen and Genzyme.[11]

B. Columbia's Covenant Does Not Cover All Of Biogen's Or Genzyme's "Present Activity" That Potentially Infringes The '275 Patent.

1. Columbia's Covenant Excludes All Infringing Activity After September 1, 2004

Columbia moves to dismiss for lack of subject matter jurisdiction on the grounds that the Covenant in this case has the same effect as that in *Super Sack Manufacturing Corp. v. Chase Packaging Corp.*, 57 F.3d 1054 (Fed. Cir. 1995). *See* Columbia's Mem. Supp. Emergency Mot. to Dismiss, at 7 (MDL Docket No. 87). However, while Columbia blindly tracked the language of the *Super Sack* covenant, the facts of this case are nothing like those in *Super Sack*. In *Super Sack*, the declaratory judgment plaintiff "never contended that it [had] already taken meaningful preparatory steps toward an infringing activity by planning to make a new product that may later be said to infringe." *Id.* at 1059–60. It was only the existing commercial products that potentially infringed. Thus, the Covenant not to sue on any current or past commercial product sufficed to eliminate the actual controversy. Similarly, in *Ultratech*, the defendant had no concrete plans to engage in activities that could constitute infringement in the future. *Ultratech*, Mem. Op. at 7. Moreover, Ultratech's "amorphous plans" were unsupported by any affidavits. *Id.*

---

[10] *See* June 22 Hearing Transcript, at 54, 57, 84 (Tab 15). Columbia made a similar statement before the Judicial Panel on Multidistrict Litigation. *See* Tr. of Oral Argument, at 4, *In re Columbia University Patent Litigation*, 313 F. Supp. 2d 1382 (J.P.M.L. 2004) (MDL No. 1592) (Tab 16).

[11] Biogen Termination Letter (Tab 9); Genzyme Termination Letter (Tab 10).

REDACTED

Unlike *Super Sack*, or any of the other cases Columbia discusses in its brief, the patent at issue here covers activity that is performed *during the process of discovering, developing, testing and manufacturing* a drug for commercial sale—the patent does not cover the commercial product itself. The '275 patent essentially claims tools for improving drug development, like a patent on starting materials or on a process for speeding up drug discovery. One would infringe the '275 patent by, for example, by doing scientific research that uses a cotransformed CHO cell according to claim 1; that involves cotransforming a CHO cell and recovering the protein it produces in the way described in claim 2; or that requires a scientist to make or use a DNA construct such as that set out in claim 20. Because the patent is infringed, if at all, *during* the research and development process, and because plaintiffs are engaged in current and ongoing research and development, this case is entirely unlike *Super Sack* or any of the other cases cited by Columbia. *Cf. Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991) ("Spectronics can not demonstrate that its present activity is potentially infringing of any patent claims."), *abrogation on other grounds recognized by Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 355 F.3d 1361 (Fed. Cir. 2004); *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 854–55 (Fed. Cir. 1999) (court held that a plaintiff's generalized, unsupported fear of suit was not enough to support jurisdiction).

The recent Federal Circuit decision in *Sierra Applied Sciences, Inc. v. Advanced Energy Industries, Inc.*, 363 F.3d 1361 (Fed. Cir. 2004), which involved a company's internal use of a potentially infringing method of using a power supply, is instructive. The *Sierra* court remanded a declaratory judgment claim that had been dismissed for lack of subject matter jurisdiction,

holding that if it turned out the particular power supply at issue (the Coleman 150 kW) had been used to perform the patented method internally—"even if only briefly—the testing would satisfy the 'activity' prong" of the case-or-controversy test and allow the declaratory judgment action to go forward. *Id.* at 1377.

As explained in *Sierra*, there is no damages threshold for bringing suit. Even if the damages are *de minimis* and the patentee would not, as a practical matter, bring suit with respect to the potentially infringing activity—such as a single internal use of a patented method—the potentially infringing conduct is sufficient to satisfy the jurisdictional threshold provided that the patentee's actions have created a reasonable apprehension of suit. *Id.* at 1376–77. "By not making a promise not to sue of a breadth equal to its threats," the patentee in *Sierra*—and Columbia here—fails to eliminate the reasonable apprehension of suit it created. *Id.* at 1375.

REDACTED

In other words, if Biogen and Genzyme infringe the '275 patent at all in connection with their research and development of recombinant drugs, they infringe today, and Columbia's covenant not to sue them for infringement up to September 1, 2004, does nothing to eliminate the reasonable apprehension of suit with respect to their activity today, tomorrow and in the coming months.

REDACTED

cf. DuPont Merck Pharm. Co. v. Bristol-Myers Squibb Co., 62 F.3d 1397, 1401 (Fed. Cir. 1995) (noting that plaintiffs had spent "much money" in preparation for the potentially infringing activity); *Kos Pharm., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d 311, 318 (S.D.N.Y. 2003) (observing that the plaintiffs' intention to engage in potentially infringing activity was evident from the money and time it had spent in preparation).

By excluding from the Covenant plaintiffs' current, ongoing, and future use of cotransformed CHO cells for the development of new proteins, Columbia has failed to provide any assurance whatsoever that it will not sue at its earliest opportunity. Faced with a high probability of suit, Biogen and Genzyme should not be required to bear the burden of risk, uncertainty and potential accrual of royalty claims while Columbia picks the time and place it wants to sue. A leading treatise on federal procedure notes that

> the Declaratory Judgment Act . . . is intended to minimize the danger of avoidable loss and the unnecessary accrual of damages and to afford one threatened with liability an early adjudication without waiting until an adversary should see fit to begin an action after the damage has accrued.

10B Wright et al., *Federal Practice and Procedure* § 2751, at 457 (3d ed. 1998). Nor should Biogen and Genzyme be forced to make scientific decisions about what research and development to pursue, and to make financial decisions about how much to invest in potentially infringing projects, with the cloud of uncertainty hanging over their heads. If Columbia's patent is invalid and unenforceable, Biogen and Genzyme should not have to consider altering their

research and development strategies to design around Columbia's patent. The acute uncertainty that plaintiffs currently face is exactly the kind of situation that the Declaratory Judgment Act was intended to remedy.

2. The Covenant Does Not Extend to Affiliates.

Faced with requests for clarification from numerous plaintiffs, Columbia adamantly refused to extend the Covenant to affiliates of the named plaintiffs. Once again, Columbia's goal seems to be to do the minimum it thinks it can get away with while leaving the threat of litigation over the '275 patent looming over every major U.S. biotechnology company. It overlooks the fact that these companies, all of them public, report their earnings on a consolidated basis with their affiliates. The threat that Columbia will sue affiliates of Biogen or Genzyme impacts them, their scientists and their managers in an immediate and tangible way. The reasonable apprehension of such suit plainly gives rise to an actual controversy, in which the legal interests of the parties in the validity and enforceability of the '275 patent are directly adverse.

In this case, moreover, Biogen's affiliate, Biogen Idec, Inc., is the successor to Idec Pharmaceuticals, Inc., which itself has developed and manufactured recombinant therapeutic drugs in contransformed CHO cells. Complaint, ¶¶ 7-8, *Biogen Idec Inc. v. Trs. of Columbia Univ.*, No. 04-CV-12009-MLW (D. Mass. filed Sept. 17, 2004). Biogen Idec, Inc. has a reasonable apprehension that it will be sued on the '275 patent by Columbia that is based upon Columbia's express refusal to include affiliates in the Covenant, its repeated threats to various licensees, and the fact that, prior to merging with Biogen, Biogen Idec, Inc. never had the protection of any license agreement with Columbia, as set forth in the recently filed complaint assigned to this Court. Complaint, ¶ 14, *Biogen Idec Inc. v. Trs. of Columbia Univ.*, No. 04-CV-12009-MLW (D. Mass. filed Sept. 17, 2004). The issue of the validity and enforceability of the '275 patent thus will remain an issue to be determined by this Court, and it is an issue of singular

importance to the named plaintiffs *and* their affiliates. Columbia's refusal to extend the Covenant to affiliates of the named plaintiffs is further reason to deny Columbia's motion to dismiss.

C. Columbia's Purported Reinstatement of Biogen's and Genzyme's Licenses, Even If Effective, Does Not Eliminate The Actual Controversy.

After the close of business on Monday of this week--eighteen days after filing its motion to dismiss and just *forty-eight hours* days before this brief was due--Columbia's counsel wrote a letter to counsel for plaintiffs asserting as an additional argument that the "Federal Circuit's decision in *Gen-Probe* forecloses Biogen and Genzyme from pursuing its declaratory relief claims against Columbia, and "suggest[ing] that you include any arguments on this issue in your clients' opposition to the Motion to Dismiss, as Columbia intends to address the implications of *Gen-Probe* in its reply." Columbia's counsel offered no explanation or excuse for its tactic of raising this argument for the first time in its reply, and Columbia refused requests by Biogen, Genzyme, and Abbott that they be permitted to extend the briefing schedule by one or two days in order to respond to Columbia's tardy disclosure of its *Gen-Probe* argument.[12]

In its letter, Columbia asserted that the present case is "no different" from *Gen-Probe*, in which the Federal Circuit held that the existence of a license, "unless materially breached, obliterated any reasonable apprehension of a lawsuit." *Gen-Probe* Letter (citing *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1381–82 (Fed. Cir. 2004), *petition for cert. filed* (U.S. Aug. 20, 2004) (No. 04-260)) (Tab 19). But this case is not the *Gen-Probe* case. In March 2004,

---

[12] Biogen, Genzyme and Abbott initially requested a two-day extension of the deadline for filing this opposition brief. Columbia refused. Columbia then refused a requested a one-day extension. In light of Columbia's insistence that plaintiffs brief the *Gen-Probe* issue in two business days, Biogen and Genzyme respectfully reserve the right to respond more fully once Columbia presents this issue in its reply brief.

Columbia terminated Genzyme's license on two grounds—failure to pay royalties and failure to submit required reports—and Biogen's on three grounds—asserting in addition that Biogen had failed to pay required fees. *See* Biogen Termination Letter (Tab 9); Genzyme Temination Letter (Tab 10). Despite their receipt of Columbia's letters, neither Biogen nor Genzyme took any steps to cure the asserted breaches, and it is undisputed that neither has submitted any quarterly sales reports to Columbia since at least 2002.

According to the licenses, the licensee is required to report net sales of licensed products "[w]ithin 90 days after the close of each calendar quarter" during the term of the [license], including the calendar quarter following termination of the [license]." Biogen License § 4(a) (Tab 2); Genzyme License § 4(a) (Tab 3). These reports are due each quarter whether or not any royalties have accrued. By the express terms of the licenses, a "Licensee shall be in material breach of this Agreement if it fails to make all reports . . . when due." Biogen License § 5(b) (Tab 2); Genzyme License § 5(b) (Tab 3).

When, on September 13, 2004, Columbia stated its desire to reinstate these licenses, it expressly limited its "withdrawal" of the notice of termination, stating that it was "*not waiving any grounds for termination of the* [*licenses*]*, except for the failure to pay royalties based on the '275 patent* ...." *See* License Letters (Tab 14) (emphasis added). Even assuming that Columbia has the power effectively to undo its prior termination of the licenses, Columbia still insists on the right to terminate Biogen or Genzyme on any other ground, including the other grounds asserted in its March 2004 termination letter and not withdrawn. In short, Columbia could turn around the day after a decision dismissing this action and send new termination letters. To achieve its forum-shopping goal, it would then need only to file suit for infringement in another jurisdiction.

Columbia's express reservation of the right to terminate at a time of its choosing creates a reasonable apprehension of suit and puts Columbia at odds with the facts of *Gen-Probe*. An earlier Federal Circuit decision, *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874 (Fed. Cir. 1983), squarely addressed the case in which a licensor chooses not to terminate its license despite allegations of breach. In *C.R. Bard*, the fact that the licensor could at any point give notice of termination license sufficed to create a reasonable apprehension of suit and an actual controversy sufficient to maintain declaratory judgment jurisdiction.

The plaintiffs should not be forced to operate their businesses *in terrorem*, with the threat of license termination and an infringement suit. *See Lear*, 395 U.S. at 670–71 (overturning the doctrine of licensee estoppel); *C.R. Bard*, 716 F.2d at 875 (not requiring termination before allowing licensees to challenge a licensed patent).

II. Plaintiffs' Contract and Tort Claims Will Necessarily Involve a Determination of the Validity and Enforceability of the '275 Patent.

In addition to the declaratory judgment counts discussed above, Biogen and Genzyme have filed, in a second, related action, supplemental claims for abuse of process, breach of contract, and unfair and deceptive trade practices (Mass. Gen. Laws ch. 93A) ("Supplemental Claims"), based upon Columbia's actions after the filing of this complaint. *See* Complaint ¶¶ 66–84, *Biogen Idec Inc. v. Trs. of Columbia Univ.*, No. 04-CV-12009-MLW (D. Mass. filed Sept. 17, 2004) (Tab 22). Since those claims concern occurrences "that have happened since the date of the pleading" in this case, *see* Fed. R. Civ. P. 15(d), they are properly considered by the Court within the context of this case. Plaintiffs' second action has been assigned to this Court as a related case, and plaintiffs intend either to seek consolidation of the new case with this case or to add the new claims to this case under Rule 15(d). These claims, which seek damages for harm to Biogen and Genzyme caused by Columbia's prior assertion of the '275 patent, are not mooted

by the Covenant. Indeed, Columbia concedes that there is subject matter jurisdiction over its own breach of contract counterclaims, as well as Genentech's breach of contract claim. Columbia Mem. at 3.

As set forth in the new complaint, an element of each of Biogen's and Genzyme's Supplemental Claims is proof of the invalidity and/or unenforceability of the '275 patent. In these counts, plaintiffs claim that Columbia improperly sought to enforce its invalid and unenforceable patent through, for example, abusing and manipulating court processes and unfairly leveraging its patent in efforts to extract illegitimate financial gain. In order to determine whether Columbia's actions were justifiable, the Court will necessarily need to determine the validity and enforceability of the '275 patent. Because Biogen and Genzyme are entitled to a determination of these issues under the Supplemental Claims, the Court clearly has jurisdiction to resolve them. *See Fina*, 141 F.3d at 1483–84 (finding that where a covenant not to sue did not resolve all of the issues presented in the complaint, subject matter jurisdiction existed).

CONCLUSION

For all the above reasons, Columbia's motion to dismiss should be denied.

Dated: September 22, 2004

Respectfully submitted,

Donald R. Ware (BBO # 516260)
Claire Laporte (BBO # 554979)
Sarah Cooleybeck (BBO # 631161)
Carla Miriam Levy (BBO # 654212)
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02210-2600
Telephone: (617) 832-1000
Facsimile: (617) 832-7000
Attorneys for BIOGEN IDEC MA INC. and
GENZYME CORPORATION